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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/722,191	11/24/2003	Richard Gribbons	PA1700 US	6737	
	28390 7590 07/14/2008 MEDTRONIC VASCULAR, INC.			EXAMINER	
IP LEGAL DEPARTMENT			HOUSTON, ELIZABETH		
3576 UNOCAL PLACE SANTA ROSA, CA 95403			ART UNIT	PAPER NUMBER	
			3731		
			NOTIFICATION DATE	DELIVERY MODE	
			07/14/2008	ELECTRONIC	

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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rs.vasciplegal@medtronic.com

	Application No.	Applicant(s)
	10/722,191	GRIBBONS ET AL.
Office Action Summary	Examiner	Art Unit
	ELIZABETH HOUSTON	3731
The MAILING DATE of this communication ap Period for Reply	ppears on the cover sheet with the o	correspondence address
A SHORTENED STATUTORY PERIOD FOR REPI WHICHEVER IS LONGER, FROM THE MAILING I - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATION  .136(a). In no event, however, may a reply be tired will apply and will expire SIX (6) MONTHS from the, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. ED (35 U.S.C. § 133).
Status		
Responsive to communication(s) filed on <u>27 J</u> This action is <b>FINAL</b> . 2b) ☐ Th     Since this application is in condition for allowed closed in accordance with the practice under	is action is non-final. ance except for formal matters, pro	
Disposition of Claims		
4)  Claim(s) 1-9 is/are pending in the application 4a) Of the above claim(s) is/are withdra 5)  Claim(s) is/are allowed. 6)  Claim(s) 1-9 is/are rejected. 7)  Claim(s) is/are objected to. 8)  Claim(s) are subject to restriction and/	awn from consideration.	
9) The specification is objected to by the Examir 10) The drawing(s) filed on is/are: a) ac Applicant may not request that any objection to the Replacement drawing sheet(s) including the corre 11) The oath or declaration is objected to by the E	ccepted or b) objected to by the e drawing(s) be held in abeyance. Se ction is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreig a) All b) Some * c) None of:  1. Certified copies of the priority documer 2. Certified copies of the priority documer 3. Copies of the certified copies of the pri application from the International Burea * See the attached detailed Office action for a list	nts have been received. nts have been received in Applicat ority documents have been receive au (PCT Rule 17.2(a)).	ion No ed in this National Stage
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4)  Interview Summary Paper No(s)/Mail D 5)  Notice of Informal F 6)  Other:	ate

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#### **DETAILED ACTION**

## Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claim 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,905,477 in view of Arenas (USPN 5,242,430). Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the patent claim all the limitations in the instant claims except for the guide member having an outer member being selectively rotatable around the inner member. Arenas discloses a catheter handle having an inner member and an outer member (14) that is selectively rotatable relative to and around the inner member (12). The outer member is smooth on the outer surface and the inner surface (Fig. 1) and is decoupled from the inner member so that it

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rotates freely from the inner member (C4: L31-43). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the rotatable outer member into the guide member of the patent in order to enhance the device by providing a grip that is easier for the user to hold while allowing rotation of the catheter for steering through tortuous vasculature (C1: L36-46). The feature of textured surface for improving the grip is an obvious feature that is well known in the art for improving grip.

### Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claim 1-5, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (USPN 5,334.187) in view of Arenas (US 5,242,430)
- 1. Fischell discloses a catheter and guide wire exchange system comprising:
  - a. An elongate flexible catheter shaft (20) having proximal and distal shafts and first (23) and second (22) lumens extending there through, the first lumen being open at the shaft distal end (55) and being sized and shaped to slidably receive a guide wire (12);
  - b. A longitudinal guide way (25) formed in the proximal shaft to enable transverse access to the first lumen through the proximal shaft, the guide way

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extending along a major portion of the length of the proximal shaft from a location adjacent a proximal end of the proximal shaft to a distal terminal end proximal of a distal end of the proximal shaft, thereby defining an uncut distal segment of the proximal shaft (23);

- c. A balloon mounted about a distal segment of the distal shaft (54), the balloon being in fluid communication with the second lumen;
- d. And a guide member (30) mounted on the proximal shaft and having an inner member (41). The inner member has a catheter passageway (38) extending there through for slidably receiving the catheter shaft (21) and a guidewire passageway (43) for slidably receiving a guidewire (12) (see Fig. 5) for merging the guide wire and the catheter by guiding the guide wire transversely through the guide way and into the first lumen and for separating the guide wire and catheter by guiding the guide wire transversely out of the first lumen through said guide way (C4: L35-C6: L20), the guide member including a keel (47) for tracking the guide way.
- e. The keel (47) has a passageway for receiving the guidewire and the inner member has a guidewire passageway in communication with the keel guidewire passageway. The guidewire passageway of the inner member is in communication with the keel guide wire passageway (Figs. 4c and 6).
- 4. Fischell does not disclose an outer member on the guide member.
- 5. Arenas discloses a catheter handle having an inner member and an outer member (14) that is selectively rotatable relative to and around the inner member (12).

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The outer member is smooth on the outer surface and the inner surface (Fig. 1) and is decoupled from the inner member so that it rotates freely from the inner member (C4: L31-43). Arenas states having a handle with a rotatable portion is an advantage because it allows the use to have a stationary portion for more easily gripping while having a rotatable portion for rotationally steering the catheter through tortuous vasculature (C1: L36-46).

- 6. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the rotatable outer member into the handle/guide member of Fischell in order to enhance the device by providing a grip that is easier for the user to hold while allowing rotation of the catheter for steering through tortuous vasculature.
- 7. Claims rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell in view of Arenas as applied to claim 1 above, and further in view of Farivar (US 5,250,036).
- 8. Fischell modified by Arenas discloses the invention substantially as claimed except for the outer member having a textured surface with circumferential bosses. However Farivar discloses a catheter handle having circumferential bosses (63) in order to provide a desired contour for efficient grasping and manipulation of the device (C6: L62-68). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a textured surface into the handle in order to improve the grasping capabilities.

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### Response to Arguments

2. Applicant's arguments with respect to claims 1-3 have been considered but are moot in view of the new ground(s) of rejection.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/E. H./ Examiner, Art Unit 3731

/Todd E Manahan/ Supervisory Patent Examiner, Art Unit 3731